

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) <b>101896-0208</b>	
	Application Number <b>10/664,575-Conf. #3611</b>		Filed <b>September 17, 2003</b>
	First Named Inventor <b>Jonathan Fanger and Eric D. Kolb</b>		
	Art Unit <b>3733</b>	Examiner <b>Swiger III, James L.</b>	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record.</p> <p>Registration number <u>44,238</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.</p> <p>Registration number if acting under 37 CFR 1.34. _____</p> <p><u>Lisa Adams</u> Signature _____ Typed or printed name</p> <p>(617) 439-2000 Telephone number _____ March 20, 2007 Date _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			

<p style="text-align: center;"><b>Pre-Appeal Brief Request for Review</b></p> <p>I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).</p> <p><b>615075.1</b></p> <p>Dated: March 20, 2007      Signature: <u>Lisa Adams</u> (Lisa Adams)</p>	
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Docket No.: 101896-0208  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Jonathan Fanger et al.

Application No.: 10/664,575

Filed: September 17, 2003

For: DRILL GUIDE WITH ALIGNMENT FEATURE

Confirmation No.: 3611

Art Unit: 3733

Examiner: Swiger III, James L

Certificate of Mailing

I hereby certify that this correspondence is being electronically filed via EFS-Web to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date set forth below.

March 20, 2007

Date

By:

  
Lisa Adams, Reg. No: 44,238  
Attorney for Applicant(s)

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**COMMENTS FOR PRE-APPEAL BRIEF REVIEW**

Dear Sir:

These comments are being filed concurrently with a Notice of Appeal, and a Pre-Appeal Brief Request for Review.

**Remarks** begin on page 2 of this paper.

A clean version of the **Pending Claims** is attached hereto for the Examiner's convenience. No amendments are made.

## REMARKS

The pending Office Action addresses claims 1, 3, 7, 11, 12, 16-19, 25, 27, 28, 33, 34, and 52-62. Claims 11, 12, 26, and 34 are withdrawn from consideration. Remaining claims 1, 3, 7, 16-19, 25, 27-28, 33, and 52-63 stand rejected.

### ***Claims 1, 3, 7, 16-19, 25, 27, 28, 33, and 52-62***

Claims 1, 3, 7, 16-19, 25, 27, 28, 33, and 52-62 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,379,364 of Brace in view of U.S. Publication No. 2003/0187454 of Gill. The Examiner argues that Brace discloses a guide device as claimed, but admits that Brace fails to teach opposed tabs and a protrusion that extend distally from the guide member. Thus, the Examiner relies on Gill to disclose a device having opposed tabs as recited in claims 1 and 28, and opposed tabs and a protrusion as recited in claim 52.

The pending rejection is deficient because the Examiner has not established a prima facie case of obviousness in support of the pending rejection. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference, or references when combined, must teach or suggest all of the claim limitations. The Examiner has failed to meet all of the criteria.

With respect to the first criteria, the Examiner has failed to provide a suggestion or motivation to modify Brace in view of Gill. The Examiner argues that it would have been obvious to one having ordinary skill in the art to construct the device of Brace with the opposed tabs and protrusion taught by Gill to have better orientation between the device and the plate in their attachment. Brace, however, teaches an alignment device with first and second drill tubes (134, 136) having bushings (206, 208) disposed on the ends thereof which are configured to extend through and expand to engage a fastener hole in a bone plate to align the drill tubes (134, 136) with the holes in the plates (See Col. 9, lines 9-12). The tubes of Brace will likely provide a more secure connection than the use of tabs or a protrusion, as the tubes are configured to expand and positively engage the plate. Applicants refer the review panel to

the arguments previously presented and set forth in the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on January 16, 2007.

With respect to the second criteria, the Examiner has failed to show a reasonable expectation of success when modifying Brace in view of Gill. As explained in the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on January 16, 2007, the tubes of Brace engage the bone holes in a plate, and the remainder of the device is spaced a distance apart from the plate. There is no location on the device of Brace for tabs or a protrusion that could engage the plate to align the device with the plate, thus the combination suggested by the Examiner would not work.

With respect to the third criteria, the combined prior art references do not teach or suggest all of the claim limitations recited in independent claims 1 and 28. Claims 1 and 28 recite that the first and second lumens of the guide member are positioned *between* the first and second alignment tabs. Neither Brace nor Gill teach this feature of the claims, as agreed to by the Examiner during the telephone interview conducted on March 14, 2007. Specifically, the flange (79) disclosed by Gill, which the Examiner asserts is the alignment tabs of the claimed invention, is a single unitary component. Thus, no lumens can be positioned between the flange (79). Additionally, as the flange (79) is one single component, it cannot be both a first and second alignment tab as required by the claims.

Further, neither Brace nor Gill teach the protrusion recited in claim 52 that extends distally from the guide member and that is adapted to be disposed within a corresponding bore formed in a spinal plate. In the final Office Action, the Examiner asserted that elements 22 and 24 of Gill form a protrusion as claimed. Elements 22 and 24 are part of the prosthesis of Gill that is implanted into a patient. They are not formed on the insertion tool. Thus, neither Brace nor Gill teach both tabs and a protrusion as recited in claim 52.

Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness, and therefore claims 1, 28, and 52, and claims 3, 7, 16-19, 25, 27, 33, and 53-62 which depend therefrom, distinguish over the combination of Brace and Gill.

U.S. Serial No. 10/664,575  
Filed: September 17, 2003  
Group Art Unit: 3733  
Examiner: Swiger III, James L  
Docket No.: 101896-0208 (DEP5150)

***Conclusion***

In view of the above remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested.

Respectfully submitted,

Date: March 20, 2007

  
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**PENDING CLAIMS**

1. (Previously Presented) A guide device for use with a spinal plate having at least one pair of screw bores formed therein, the guide device comprising:
  - an elongate shaft having a proximal end and a distal end;
  - a guide member coupled to the distal end of the elongate shaft and including first and second lumens extending therethrough in fixed relation to one another; and
  - first and second opposed alignment tabs extending distally from opposed outer edges of opposed ends of the guide member such that the first and second lumens are positioned between the first and second alignment tabs, the first and second opposed alignment tabs being adapted to interact with a spinal plate to position the guide member with respect to the spinal plate such that the first and second lumens in the guide member are aligned with a pair of corresponding screw bores formed in the spinal plate.
2. (Canceled)
3. (Previously Presented) The guide device of claim 1, wherein the first and second opposed alignment tabs are adapted to non-fixedly interact with a spinal plate to align the guide member with the spinal plate.
- 4-6. (Canceled).
7. (Previously Presented) The guide device of claim 1,further comprising at least one protrusion that extends distally from the guide member and that is adapted to be disposed within a corresponding bore formed in the spinal plate.
- 8-10. (Canceled).
11. (Withdrawn) The guide device of claim 1, wherein the guide member has a substantially rectangular, elongate shape and the first and second lumens extend therethrough.

12. (Withdrawn) The guide device of claim 11, wherein the guide member includes opposed superior and inferior sides and opposed transverse sides, the transverse sides having a width that is less than a width of the superior and inferior sides.

13-15. (Canceled).

16. (Original) The guide device of claim 1, wherein a distal surface of the guide member has a shape that conforms to the shape of a spinal plate.

17. (Original) The guide device of claim 1, wherein the first and second lumens are positioned at an angle with respect to one another.

18. (Original) The guide device of claim 1, wherein the guide member comprises a first barrel having a lumen extending therethrough, and a second barrel having a lumen extending therethrough.

19. (Original) The guide device of claim 18, wherein the first and second barrels are positioned at an angle with respect to one another.

20-24. (Canceled).

25. (Previously Presented) The guide device of claim 1, wherein the first and second alignment tabs are adapted to loosely interact with a spinal plate such that the guide member can pivot with respect to the spinal plate.

26. (Withdrawn) The guide device of claim 1, wherein the first and second lumens have an adjustable length.

27. (Original) The guide device of claim 1, wherein the proximal end on the elongate shaft is

positioned at an angle with respect to a distal portion of the elongate shaft.

28. (Previously Presented) A guide device for use with a spinal plate having at least one screw bore formed therein, the guide device comprising:

an elongate shaft having a proximal end and a distal end; and

a guide member coupled to the distal end of the elongate shaft and including first and second lumens extending therethrough; and

first and second opposed alignment tabs extending distally from opposed outer edges of opposed ends of the guide member such that at least one lumen is positioned between the first and second alignment tabs, the first and second opposed alignment tabs being adapted to non-fixedly interact with a spinal plate to position the guide member with respect to the spinal plate such that the first and second lumens in the guide member are aligned with at least one corresponding screw bore formed in the spinal plate.

29-32. (Canceled).

33. (Previously Presented) The guide device of claim 28, wherein the guide member comprises first and second barrels having the first and second lumens formed therein.

34. (Withdrawn) The guide device of claim 33, wherein at least one of the first and second barrels has an adjustable trajectory such that the at least one barrel can pivot about a point on a longitudinal axis thereof.

35-51. (Canceled)

52. (Previously Presented) A guide device for use with a spinal plate having at least one pair of screw bores formed therein, the guide device comprising:

an elongate shaft having a proximal end and a distal end;

a guide member coupled to the distal end of the elongate shaft and including first and second

lumens extending therethrough in fixed relation to one another;

at least one alignment tab extending distally from the guide member, the at least one alignment tab being adapted to interact with a spinal plate to position the guide member with respect to the spinal plate such that the first and second lumens in the guide member are aligned with a pair of corresponding screw bores formed in the spinal plate; and

at least one protrusion that extends distally from the guide member and that is adapted to be disposed within a corresponding bore formed in the spinal plate.

53. (Previously Presented) The guide device of claim 52, wherein the at least one alignment tab comprises first and second alignment tabs extending distally from opposed outer edges of opposed ends of the guide member.

54. (Previously Presented) The guide device of claim 52, wherein the at least one tab is adapted to non-fixedly interact with a spinal plate to align the guide member with the spinal plate.

55. (Previously Presented) The guide device of claim 52, wherein the at least one alignment tab is adapted to prevent rotation between the guide member and a spinal plate when the guide member is mated to a spinal plate.

56. (Previously Presented) The guide device of claim 55, wherein the at least one alignment tab comprises an oval protrusion that extends distally from a distal end of the guide member.

57. (Previously Presented) The guide device of claim 52, wherein a distal surface of the guide member has a shape that conforms to the shape of a spinal plate.

58. (Previously Presented) The guide device of claim 52, wherein the first and second lumens are positioned at an angle with respect to one another.

59. (Previously Presented) The guide device of claim 52, wherein the guide member comprises a first barrel having the first lumen extending therethrough, and a second barrel having the second lumen

extending therethrough.

60. (Previously Presented) The guide device of claim 59, wherein the first and second barrels are positioned at an angle with respect to one another.

61. (Previously Presented) The guide device of claim 52, wherein the at least one alignment tab is adapted to loosely interact with a spinal plate such that the guide member can pivot with respect to the spinal plate.

62. (Previously Presented) The guide device of claim 52, wherein the proximal end on the elongate shaft is positioned at an angle with respect to a distal portion of the elongate shaft.

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